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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,356	11/25/2003	Antonio Cutando Soriano	285.1001US	4724

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/722,356	Applicant(s) SORIANO ET AL.	
	Examiner Frederick Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/04</u> . | 6) <input type="checkbox"/> Other: ____. |

Claim Informalities

The following informalities are noted:

- 1) Claim 1, second line, “a” (before “toothpaste”) should be changed to “as”.
- 2) Claim 2, fourth line, “an” (before “active”) should be deleted.
- 3) Claim 4, last line, the chemical name is incorrect and should read “N-acetyl-5-methoxytryptamine.”
- 4) Claim 5, last line, the first word on the line is spelled incorrectly and should be amended to read “hydroquinone”.

Claim Objection, Failure to Further Limit

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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Claim 4 merely recites the more formal alternative chemical name for melatonin.

The compound remains, however, melatonin; accordingly, it is not seen how claim 4 serves to limit claim 1.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, penultimate line, the weight percentage value is unclear because the basis for its determination has not been set forth.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. *See Honeywell Intl. v. Intl. Trade Commn.*, 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it).

In order to overcome this ground of rejection the examiner recommends inserting after "5%" the phrase --- of the oral hygiene product ---.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Zuckerman (USP 6,998,112).

Patentee discloses toothpastes comprising 0.25 to 2 percent by weight melatonin. See claim 1. The base for the toothpastes comprises conventional ingredients, including hydrophobic and hydrophilic excipients, and sodium benzoate as preservative (column 1, lines 40-45).

2) Claims 1, 3, 4 and 6 are rejected under 35 USC 102(b) as being anticipated by Masterson (USP 6,200,550).

Patentee discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin (column 7, line 2). The compositions contain conventional hydrophobic and hydrophilic excipients and also contain preservatives (column 8, line 51), with sorbic acid being used in working example 4 (column 12).

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rajaiah et al (USP 6,509,007) in view of Masterson et al (USP 6,200,550).

The primary reference discloses toothpastes comprising conventional hydrophilic and hydrophobic excipients, and teaches including antioxidants such as vitamin E, ascorbic acid, melatonin, and “mixtures thereof” (column 8, lines 55-62). The primary reference thus differs from the instant claims insofar as it does not specifically disclose the relative proportion of the antioxidants. It also differs from claim 6 insofar as it is silent regarding preservatives.

Generally, the incorporation of known ingredients into known compositions for their known function is obvious on its face, as well as the determination of appropriate proportions for such components. See, e.g., Sinclair & Carroll Co. v. Interchemical Corp., 325 US 327, 65 USPQ 297 (1945); In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); and In re Peterson, 315 F.3d 1325 (CA Fed 2003). The secondary reference is discussed supra, and teaches that antioxidants in toothpastes are generally used in small amounts, preferably 0.2 to 2 percent by weight. It also teaches the use of preservatives such as sorbic acid. Accordingly, it would have been obvious to have used melatonin (alone or in combination with vitamin E or ascorbic acid) in an amount of 0.2 to 2 percent by weight in formulating the primary reference compositions, as taught by the secondary reference and consistent with the reasoning of the cited precedent. Similarly, it would have been obvious to have incorporated sorbic acid for its art-recognized preservative function, in accordance with the teachings of the secondary reference and consistent with the reasoning of the cited precedent.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday through Friday from 9:30AM to 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschell, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
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